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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,872	08/27/2001	Jean Ackermann	20757	4842

151 7590 02/27/2002
HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
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EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 02/27/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/939,872

Applicant(s)
Ackermann, J. et al.

Examiner
CHARANJIT AULAKH

Art Unit
1625



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above, claim(s) 9, 28-41, and 64-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-27, 42-63, and 67-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☒ Interview Summary (PTO-413) Paper No(s). 6
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 20) ☐ Other:

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DETAILED ACTION

1. Claims 1-75 are pending in the application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 10-27, 42-63 and 67-75, drawn to compounds of formula (I) or (Ia) where W and X represent SO₂ or SO₂NR₁, pharmaceutical composition containing these compounds and a method of using these compounds, classified in class 546, subclass 216+.

II. Claims 1-7, 9-41, 59, 60, 62-66 and 73-75, drawn to compounds of formula (I) or (Ia) where W and X are other than defined above for group I, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 544, subclass 145+.

3. The inventions I and II as defined above are patentably distinct, each from the other since they are structurally so divergent that a reference showing compounds of invention I would not render compounds of invention II prima facie obvious. Search required for e.g ; compounds of invention I in class 546 is not the same search required for e.g ; compounds of invention II in class 544 and therefore, constitutes a burdensome search. Thus, restriction requirement as indicated above is proper.

4. During a telephone conversation with the applicant's attorney, Mr. F. Aaron Dubberley on Jan. 29, 2002, a provisional election was made with traverse to prosecute the invention of group I (compound of example 17.6 as species) , claims 1-8, 10-27, 42-63 and 67-75. Affirmation of this

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election must be made by applicant in replying to this Office action. Claims 9, 28-41 and 64-66 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. It is of note that group II is subject to further restriction in the future applications based on the values of variables W and X.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-8, 10-27, 42-63 and 67-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claims 1 and 24 as well as in claims 43, 44, 47, 49, 51, 53-58, 61 and 68-71, the term ----pharmaceutically acceptable esters ---- is indefinite since it is not clear where and how the ester is being formed. The applicants are suggested to delete this term to overcome this rejection.

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In claim 59, V is defined as S. Claim 59 is indirectly dependent upon claim 24. According to the definitions of variable V in claim 24, V can not be S. An appropriate correction is required.

In claim 73, the applicants are suggested to use the term ---preparation --- instead of ---manufacture----.

In claim 75, the term ---OSC--- is vague and indefinite since its meaning is not clear. The applicants are suggested to define it. Also, the applicants are suggested to include the term ---in a mammal--- after diseases in line 1 and furthermore, include the term ---therapeutically effective amount of ---- after administering in line 5.

IMPROPER MARKUSH GROUP

8. Claims 1-7, 10-27, 60, 62, 63 and 73-75 are objected as being directed to Improper Markush Group since the variables W and X are critical for the common core of the instant compounds.

The applicants are suggested to amend the claims to read upon the elected group to overcome this objection.

Allowable Subject Matter

9. The following is a statement of reasons for the indication of allowable subject matter:

The instant compounds directed to the elected group are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the prior art, Evanega (U.S. Patent no. 3,914,426) discloses piperidinesulfonylurea derivatives for lowering blood sugar levels which are closely related to the instant compounds (see claims 1-13). However, the compounds of

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Evanega differ from the instant compounds in having different A1, A2, A5 groups in the instant compounds of formula (I) or A11, A12 and A15 groups in the instant compounds of formula (Ia) and furthermore, there is no teaching or suggestion in the prior art to modify the compounds of Evanega to prepare the instant compounds.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chana Aulakh whose telephone number is (703) 305-4482. The examiner can normally be reached on "Monday-Thursday" from 7:30 A.M. to 6:00 P.M.

If the attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Alan Rotman, can be reached on (703) 308-4698. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist whose telephone number is (703) 308-1235.


CHARANJIT S. AULAKH

PRIMARY EXAMINER